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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,872	12/04/2000	Tony Wai-Chiu So	A33477 PCT U	5826

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TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/673,872	Applicant(s) WAI-CHIU SO ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,8-17,19-21,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,8-17,19-21,23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt of Amendments and Arguments received on January 27, 2005 is acknowledged. Claims 1-4,6,8-17,19-21,23 and 24 are pending in this application. Claims 5, 7, 18, 22, and 25 stand cancelled.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 1/27/05 has been considered by the examiner. However, JP 11349451 and JP 3-127788 have not been considered since applicant has not provided the office with a copy of the foreign patent documents. Note that 37 CFR 1.98(a)(2) requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Further, the IDS of 7/21/03 has been considered except for the documents that have not been initialed since the applicant has not provided the office with a copy of the respective foreign patent documents and non-patent literature.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**The rejection of claims 1-6, 8-9, and 12-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending**

**Application No. 10/124197 (allowed January 2005) is maintained.**

Although the conflicting claims are not identical, they are not patentably distinct from each other since the subject matter claimed in both applications is similar.

Instant application is directed to a topical composition containing A) at least 5% of a piperidinopyrimidine, B) an acid selected from the group consisting of hydrochloric acid, sulphuric acid, nitric acid, and phosphoric acid, or an organic acid selected from the group consisting of citric acid, acetic acid, succinic acid, maleic acid, benzoic acid, lactic acid and mixtures thereof, C) a solvent selected from water and/or a lower alcohol, and D) a co-solvent selected from an aromatic or polyhydric alcohol in the amount of less than 10%, wherein the composition is in the form of a solution, tonic, ointment, mousse, a foam, shampoo, an aerosol, gel, paste, and cream.

Co-pending application is directed to a topical composition containing A) at least 5% of a piperidinopyrimidine, B) an acid selected from the group consisting of hydrochloric acid, sulphuric acid, nitric acid, and phosphoric acid, or an organic acid selected from the group consisting of citric acid, acetic acid, succinic acid, maleic acid, benzoic acid, lactic acid and mixtures thereof, C) a solvent selected from water and/or a lower alcohol, and D) a co-solvent a co-solvent of a polyhydric alcohol selected from 3-butylene glycol, polyethylene glycol,

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hexylene glycol, dipropylene glycol, glycerol or propylene glycol at less than approximately 10% by weight, wherein the final product is a foam or a mousse.

Thus, the instant subject matter is the generic scope in relation to the species claimed in co-pending application. Therefore, the co-pending claims are encompassed by instant claims.

### ***Response to Arguments***

Applicant's arguments filed 1/27/05 have been fully considered but they are not persuasive. Applicant argues that a Terminal Disclaimer has been filed in application 10/124197 and thus rendering the instant double patenting rejection moot.

The examiner points out that a Terminal Disclaimer must be filed in each application and a Terminal Disclaimer filed in a continuation does not transfer to related applications.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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**The rejection of claims 1-3, 6, 8-9, 12-17, 19, 21, and 23 under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5183817) by itself or optionally in view of WO 97/12602 is maintained.**

Bazzano teaches a minoxidil composition to increase growth rate and stimulate new hair growth by administering a lotion containing 0.01-0.1% retinoic acid, 0.5-5% minoxidil, ethanol, 5-50% propylene glycol, 0.1% BHT, and distilled water (up to 10%). Formulation example II contains 1% retinoic acid, 10% minoxidil, 4% cetyl alcohol, 4% ethanol, and up to 100% water. Bazzano teaches the use of pharmaceutically acceptable acid salt. See column 19, lines 1-25. Bazzano states that minoxidil or its derivatives and analogs that are described in US patents 5910928, 3637697, 3461461, 4139619, and 4596812 are incorporated into the reference. US patent 3,461,461 teaches the acid salt derivatives including lactic acid and other instantly claimed acids of minoxidil. Bazzano discloses that a major problem in influencing hair growth is obtaining good percutaneous absorption of the active compounds. The retinoid compounds cause excellent absorption of the hair follicles. See column 19, lines 35-40. The formulation can contain any pharmaceutically acceptable carrier, additive, or solubilizer.

Although Bazzano states that a minoxidil derivative/analog may be utilized, Bazzano does not explicitly teach the use of an acid addition.

WO teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Minoxidil is modified by reacting it with an organic acid such as lactic acid. See page 4.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Bazzano and utilize instant minoxidil acid salt. One would

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be motivated to do so since Bazzano teaches the suitability of minoxidil or its derivative in the composition and Bezant's teachings incorporate other US patents wherein the instant acid salt derivative is taught. Therefore, one could reasonably expect similar results with the use of a minoxidil acid salt derivative.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made look to the teachings of WO and be further motivated to utilize the instant acid derivative. One would have been motivated to do so since both references teach that by adding salt to minoxidil, one obtains a more soluble form of the active. Further, WO teaches this addition to yield a hydrophilic compound, allows for better penetration into the hair follicles. Further, since Bazzano is concerned with penetration of the composition into the hair follicle one would expect an additive effect of increasing penetration of the composition by adding instant salt. Lastly, WO demonstrates that it is known in the art to add a salt to increase solubility of an insoluble active.

#### ***Response to Arguments***

Applicant argues that examiner has impermissibly used additional references, which are not positively recited in the rejection. Applicant argues that Bazzano teaches a retinoid, which is an essential ingredient in the formulation. Thus, applicant argues that a skilled artisan would not have been motivated to exclude Bazzano's retinoid. The applicant further asserts that claim language is not the test for obviousness and the test for obviousness is whether the combined references teach all the limitations.

Applicant's arguments filed 1/27/05 have been fully considered but they are not persuasive. Firstly, it is pointed out that when information is incorporated by reference, the

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information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. See MPEP 2163.07. Thus, in instant case Bazzano clearly incorporates US 5910928, 3637697, 3461461, 4139619, and 4596812 by reference and therefore the entire disclosure of these cited patents are part of Bazzano's disclosure. Therefore, the examiner does not have to positively recite these references in the rejection since they are part of Bazzano's disclosure itself. The examiner points out that the applicant has inappropriately applied *In re Hoch*. In *In re Hoch*, the examiner relied on a reference to demonstrate a property of a compound and this reference was not incorporated by reference. Therefore, the board held that the reference must be positively recited in the rejection since it was pertinent to the examiner's rejection.

With regard to applicant's argument that Bazzano's formulation contains a retinoid, the examiner points out that the instant claim language is open-ended. Therefore, the instant claims language does not exclude the use of a retinoid. Moreover, since the claim language is not close-ended, the examiner need not provide a motivation to exclude a retinoid from Bazzano's formulation.

The examiner notes the test for obviousness and points out Bazzano teaches all the claimed limitations. The claims **comprise** A) at least 5% minoxidil or a salt thereof, B) an acid, C) a solvent selected from water or a lower alcohol, and D) less than 10% of a co-solvent selected from an aromatic or polyhydric alcohol. Bazzano teaches a lotion comprising A) 0.5-5% minoxidil, C) ethanol and distilled water, and D) 5-50% propylene glycol. Further, US patent 3,461,461, which is incorporated by reference, teaches the acid salt derivatives including lactic



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acid and other instantly claimed acids of minoxidil. Thus, it can be clearly seen that Bazzano by itself suggests all the instantly claimed limitations.

Applicant argues that Weiner et al does not cure the deficiencies of Bazzano. Applicant argues that although Weiner teaches modifying minoxidil with the instant acids to make it more hydrophilic, Weiner teaches the encapsulation of the modified active in a lipid vesicle. The applicant argues that the instant invention does not require the lipid vesicle.

Firstly, it is pointed out that the examiner relies on Weiner for its specific teachings that a modifying minoxidil with instant salts provide a hydrophilic active. Weiner teaches the use of a salt derivative to further increase the penetration of minoxidil. Again the examiner points out that the instant claim language, "comprising", does not exclude other components in the formulation. Therefore, the scope of the instant claims allows for Weiner's lipid vesicles.

Accordingly, the rejection is maintained.

**The rejection of claims 1-4, 5-6, 8-9, 12-19, 21-23 under 35 U.S.C. 103(a) as being unpatentable over WO 95/25500 to Navarro et al (abstract only) in view of WO 97/12602 to Weiner et al is maintained.**

Navarro teaches a hair care composition containing 0.1-7% minoxidil, 0.1-3% cyclodextrin, 0.5-10% minoxidil solvent (propylene glycol), 30-50% monoalcohol (ethanol or isopropanol), and water. Note abstract and examples.

Navarro does not teach the use of lactic or acetic acid.

Weiner teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Weiner teaches that a number of different modifications may be made to the minoxidil. One such modification is provided by ]

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reacting minoxidil with an organic acid such as lactic acid. The minoxidil may also be converted to a salt by reacting it with a cyclodextrin. See page 3. Weiner states that the use of a minoxidil acid salt addition provides substantial penetration and cyclodextrin salt addition is the “next best”. See page 7.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Navarro et al and Weiner et al and substitute Navarro’s cyclodextrin with the instant acid to convert minoxidil into a salt. One would be motivated to do so since Weiner teaches that by converting the minoxidil to a hydrophilic compound, it penetrates the skin. More specifically, Weiner teaches the conversion of minoxidil into a salt form by reacting it with an organic acid such as instant lactic acid or with cyclodextrin and notes that although both provide penetration of minoxidil, the acid salt addition has a better effect than the cyclodextrin salt addition. Therefore, one would have been motivated to use an acid salt addition to convert minoxidil into a hydrophilic compound rather than Navarro’s cyclodextrin since Weiner teaches the acid salt addition has better penetration into the skin.

### ***Response to Arguments***

Applicant argues that the prior art references teach the encapsulation of minoxidil. Applicant argues that Navarro teaches encapsulating minoxidil with a cyclodextrin carrier. Applicant argues that Weiner teaches the use of a lipid vesicle to encapsulate the minoxidil salt. Applicant argues that the examiner’s motivation to substitute Navarro’s cyclodextrin encapsulation with Weiner’s encapsulation would destroy the aim of Navarro.

Applicant's arguments filed 1/27/05 have been fully considered but they are not persuasive. The examiner notes that Weiner indicates that an encapsulated lactic salt of

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minoxidil has greater penetration than unencapsulated form. However, the examiner again points out that the instant claim language is open-ended. Therefore, the instant claims language does not exclude Weiner's lipid vesicle.

With regard to the examiner's motivation, the examiner points out that Weiner clearly compares Navarro's cyclodextrin encapsulation of minoxidil with a liposome encapsulated minoxidil lactate and teaches the liposome encapsulated minoxidil lactate is better than Navarro's encapsulation. Therefore, this is a clear motivation to substitute Navarro's cyclodextrin encapsulated minoxidil with Weiner's liposome encapsulated minoxidil lactate since the latter affords better penetration. The examiner points out to establish a prima facie case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Clearly, Weiner provides a motivation to modify Navarro's invention. Furthermore, there is a reasonable expectation of success since both references are directed increasing the topical penetration of minoxidil.

Accordingly, the rejection is maintained.

**The rejection of claims 10-11, 20, and 24 under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5183817) in view of WO 97/12602, in further view of Uchikawa et al (5156836) is maintained.**

Bazzano teaches a minoxidil composition to increase growth rate and stimulate new hair growth by administering a lotion containing 0.01-0.1% retinoic acid, 0.5-5% minoxidil, ethanol, 5-50% propylene glycol, 0.1% BHT, and distilled water (up to 10%). WO teaches reacting

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minoxidil with an organic acid such as lactic acid to increase its penetration into the skin. See page 4.

The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol and benzyl alcohol. Further, the reference teaches a formulation where the alcohol-water mixture is in the instant ratio. (col. 3 and 4, line 45 through line 34). Uchikawa et al teaches the application of the hair composition for the treatment of hair loss.

It would have been obvious at the time the invention was made to combine the teachings of Bazzano, WO, and Uchikawa and utilize benzyl alcohol in the solvent system. One would have been motivated to do so since Uchikawa et al teach the use of either ethanol or benzyl alcohol as functional equivalents, i.e. solvents, in the hair tonic. Therefore, it is prima facie obvious to substitute one equivalent solvent for another, i.e. Bazzano's ethanol with instant benzyl alcohol, since the prior art establishes that both are functionally equivalent and are utilized for the same purpose.

### ***Response to Arguments***

Applicant argues that Uchikawa teaches the use of amine oxides and anionic surfactants in the composition and the instant invention does not contain these components.

Applicant's arguments filed 1/27/05 have been fully considered but they are not persuasive. With regard to Uchikawa's use of amine oxide and surfactants, the examiner points out that the claim language does not exclude other ingredients in the instant formulation.

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Further, the examiner notes that applicant's arguments are based on the bodily incorporation of the secondary references into the primary reference. It is pointed out that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the examiner utilizes Uchikawa for its specific teaching that ethanol and instant benzyl alcohol may be utilized as solvents in a hair compositions. It is noted applicant does not address the examiner's motivation.

Accordingly, the rejection is maintained.

**The rejection of claims 10-11, 20, and 24 under 35 U.S.C. 103(a) as being unpatentable over WO 95/03638 to Navarro et al (abstract only) in view of WO 97/12602 to Weiner et al in further view of Uchikawa et al (5,156,836) is maintained.**

As set forth above, WO teaches a hair care composition containing 0.1-7% minoxidil, 0.1-3% cyclodextrin, 0.5-10% minoxidil solvent (propylene glycol), 30-50% monoalcohol (ethanol or isopropanol), and water. Note abstract and examples. Weiner teaches reacting minoxidil with an organic acid such as lactic acid to increase its penetration into the skin. See page 4.

The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol and benzyl alcohol. Further, the reference teaches a formulation

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where the alcohol-water mixture is in the instant ratio. (col. 3 and 4, line 45 through line 34).

Uchikawa et al teaches the application of the hair composition for the treatment of hair loss.

It would have been obvious at the time the invention was made to combine the teachings of Navarro et al, Weiner et al, and Uchikawa and utilize benzyl alcohol in the solvent system. One would have been motivated to do so since Uchikawa et al teach the use of either ethanol or benzyl alcohol as functional equivalents, i.e. solvents, in the hair tonic. Therefore, it is prima facie obvious to substitute one solvent for another, i.e. WO's ethanol with instant benzyl alcohol, since the prior art establishes that both are functionally equivalent and are utilized for the same purpose.

### ***Response to Arguments***

Applicant argues the merits of Navarro and Weiner et al. Applicant argues that Uchikawa teaches the use of amine oxides and anionic surfactants in the composition and the instant invention does not contain these components.

Applicant's arguments filed 1/27/05 have been fully considered but they are not persuasive. The merits of Navarro and Weiner et al have been discussed above.

With regard to Uchikawa's use of amine oxide and surfactants, the examiner points out that the claim language does not exclude other ingredients in the instant formulation.

Further, the examiner notes that applicant's arguments are based on the bodily incorporation of the secondary references into the primary reference. It is pointed out that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of

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the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the examiner utilizes Uchikawa for its specific teaching that ethanol and instant benzyl alcohol may be utilized as solvents in a hair compositions. It is noted applicant does not address the examiner's motivation.

Accordingly, the rejection is maintained.

**The rejection of claims 1-3, 5-6, 8-9, 12-19, 21-23 under 35 U.S.C. 103(a) as being unpatentable over Di Schiena (4866067) in view of WO 97/12602 is maintained.**

Di Schiena discloses minoxidil (0.1-10%, ex: 5%) combined with oxyniactic acid for topical treatment of alopecia. The reference discloses that minoxidil is insoluble in water and the salt form of minoxidil is soluble in a water-based composition. Therefore, an acid makes it remarkably soluble in water without loading the composition with glycols. Di Schiena discloses a foam composition containing the instant active, water, a lower alcohol, and propylene glycol (9%) in a foam composition (note examples). The foam composition also contains cetyl alcohol and a surfactant. Di Schiena teaches methanol, ethanol, or isopropanol as suitable solvents (col. 2, lines 17-20 and examples. Further, the reference exemplifies a lotion containing the active without the use of a glycol, instant amount of water, ethanol, and active (example b). The examples teach a variety of water to lower alcohol ratios.

Di Schiena does not teach the use of lactic or acetic acid.

WO teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Minoxidil is modified by reacting it with an organic acid such as lactic acid. See page 4.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Di Schiena and WO and utilize the instant acids. One would have been motivated to do so since WO teaches that organic acids modify minoxidil to yield a hydrophilic active and therefore is more soluble in water and improves penetration into the hair follicle. Therefore, since Di Schiena also teaches the use of an organic acid to improve solubility it is within the skill of an artisan to substitute another acid with the expectation of similar results.

With regard to the claimed ratio of 17, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to manipulate the parameters set forth in Di Schiena. One would have been motivated to do so as part of routine experimentation to yield the best possible results. Differences in concentration do not extend patentability to subject matter encompassed in the prior art unless there is evidence-indicating criticality.

### ***Response to Arguments***

Applicant argues that applicant's July 21, 2003 Rule 132 Declaration overcomes the instant rejection since the instant invention is homogenous and Di Schiena is not.

Applicant's arguments filed 1/27/05 have been fully considered but they are not persuasive. The examiner points out that a proper comparison of the prior art and the instant invention cannot be made since applicant has not provided the ingredients that are in the "inventive composition". There are several factors that affect a composition and without the inventive composition to compare with the prior art, the examiner cannot make a reasonable



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conclusion. Further, it cannot be determined if the claims are commensurate in scope with the unexpected results since applicant has not provided the components that comprise the "inventive composition."

Accordingly the rejection is maintained.

***Conclusion***

None of the claims are allowed at this time.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

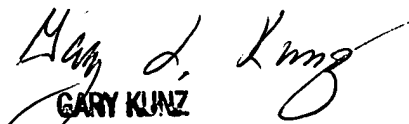
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi  
Examiner  
Art Unit 1616

SSG

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**